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| 10/570,481 | 08/25/2008 | Matthew Buderer | OSLER1140-1 | 9925 |
| 28213 | 7590 | 09/29/2011 | EXAMINER | |
| DLA PIPER LLP (US) | | | CLARK, AMY LYNN | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/570,481 | Applicant(s) BUDERER ET AL. |
| | Examiner Amy L. Clark | Art Unit 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2011.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1-9 and 18-28 is/are pending in the application.
- 5a) Of the above claim(s) 5 and 19-28 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1-4, 6-9 and 18 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1448)
 Paper No(s)/Mail Date 06/27/2011
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date, _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 06/27/2011 with the cancellation of amendment of claims 1, 2 and 6.

Election/Restrictions

The election/restriction requirement is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection found in the previous Office Action and not repeated herein has been withdrawn based upon Applicant's amendments to the claims.

Claims 1-4, 6-9 and 18 are currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/27/2011 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

Claims 1-4 remain rejected under 35 U.S.C. 102(b) as being anticipated by Xiong et al. (A*, 6299925 B1).

Xiong teaches a solid-state water soluble granular or tablet formulation comprising green tea plant extract containing polyphenols in an amount of 5-99 wt% (which reads on polyphenol, as defined by Applicant in Applicant's specification- see page 5 as an example), wherein the tea plant extract is first combined with a lubricant, wherein the lubricant can be polyethylene glycol 6000 or sodium lauryl sulfate (which reads on topical gel, since it is a gel and can be applied topically) or sodium benzoate (which

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reads on polyphenol in an anhydrous mixture) and a binder, wherein the binder can be starch (which reads on adsorbent binding carrier), celluloses, gelatin or guar gum, prior to combination with other ingredients. Xiong teaches that the combination of green tea plant extract and the binder does not require water (which reads on anhydrous) and can further include other anhydrous materials, such as citric acid and carbonate salts.

Although Xiong does not expressly teach that the tea plant extract is adsorbed onto the binding carrier, the claimed functional properties are inherent to the preparation taught by Xiong because the ingredients and the formulation of the ingredients taught by Xiong are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, the tea plant extract containing polyphenols in the presence of a lubricant would inherently be adsorbed onto a binding carrier as taught by Xiong.

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-9 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Xiong et al. (A*, 6299925 B1), in view of Hall et al. (N*, WO 03063840 A2, Abstract only).

The teachings of Xiong are set forth above and applied as before.

Hall teaches a pharmaceutical composition comprising an antacid core comprising a water impermeable film comprising shea butter. Hall further teaches that the composition can comprise talc and magnesium aluminum silicate (which is synonymous with clay and also reads on a magnesium and a silicate as a binder).

It would have been obvious to modify the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel that can be administered topically taught by Xiong with talc or the clay binder taught by Hall and further combining the adsorbed tea polyphenols with shea butter by Hall because at the time the invention was made, it was known that tea polyphenols could be combined with a binding carrier in an effervescent composition, as clearly taught by Xiong and that clay is a useful as binder in an effervescent composition and that shea butter

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can also be used in an effervescent composition to help form a water impervious layer as clearly taught by Hall.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. Based on the disclosure by that tea polyphenols can be combined with a binder and a topical gel as clearly taught by Xiong, and that clay can be used as a binder in an effervescent composition and that shea butter can be used in an effervescent composition as taught by Hall, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See MPEP section 2144.06, In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980), Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Thus, an artisan of ordinary skill would reasonably expect that modifying the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel with talc or the clay binder and shea butter would provide an even more effective anhydrous effervescent composition, because shea butter is known to be useful as a barrier against moisture to help maintain the life of the effervescent tablet based upon the teachings of Xiong and Hall. This reasonable expectation of success would motivate the artisan to modify the anhydrous effervescent composition taught by Xiong by combining polyphenols extracted from tea adsorbed on a binding carrier and gel with talc or the clay binder and shea butter based upon the teachings of Hall.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants' arguments filed 06/27/2011 with regards to the 102(b) rejection have been fully considered but they are not persuasive.

Applicants argue that Xiong is directed to an effervescent green tea formulation to be dispersed in water or another suitable liquid and waiting for it to be dissolved or disbursed. Applicants further argue that Xiong further teaches that once the formulation has become substantially dissolved or disbursed in the liquid it is orally consumed and that Xiong does not teach a topical composition or a composition in which polyphenol is adsorbed to a binding carrier.

However, this is not found persuasive because Xiong teaches the instantly claimed ingredients and teaches the combination of these ingredients. The manner in which the ingredients are combined would inherently provide a polyphenol adsorbed to an adsorbant binding carrier. With regards to the mode of administration, compositions suitable for oral ingestion can be topically applied, since a composition that is safe for oral administration would be expected to be safe for topical application. It was also known in the art at the time the invention was made that effervescent granules could be applied topically and could be added to water for bathing (which is a type of topical administration) or to steam for inhalation (which is also a form of topical administration, since the effervescent granulation can be administered to skin cells of the nose (both inner and outer) (See Forman et al., US Patent: 5948439, Reference B*, which teaches an effervescent granule for the release and efficient dispersion of an herbal preparation and modes of administration of the granules). Therefore, the rejection is maintained for the reasons of record.

Applicants' arguments filed 06/27/2011 with regards to the 103(a) rejection have been fully considered but they are not persuasive. Applicants' arguments with regards to Xiong are the same as above and the response to the arguments is the same as above. Applicants further argue that Hall is directed to a composition for the delivery of proton pump inhibitors and that the composition taught by Hall comprises an antacid core. Applicants further argue that the composition taught by Hall is for transmucosal delivery to the mouth but does not teach or suggest a topical composition, nor does Hall

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teach a polyphenol adsorbed to a binding carrier. Applicants further argue hindsight reasoning and that the cited references fail to teach or suggest the recited claim limitations

However, this is not found persuasive because transmucosal delivery is a type of topical delivery system of a formulation, since mucous membranes, which are on the surface, topically absorb the formulations. Further, it was well known in the art that antacids can be topically applied (See Bodin et al., abstract provided herein, EP 62578 A, Reference O). Therefore, the combination of the teachings of Xiong and Hall is maintained for the reasons set forth above and for the reasons set forth in the previous Office Action.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the rejections are maintained for the reasons of record and for the reasons set forth herein.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Primary Examiner, Art Unit 1655